



UNITED STATES DEPARTMENT OF COMMERCE
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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/715,031	06/10/91	COOPER	G 194/167

EXAMINER

LEE, L

ART UNIT PAPER NUMBER

189

DATE MAILED: 09/13/91

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 7-17 and 43-52 are pending in the application.
Of the above, claims 7-17 and 43-45 are withdrawn from consideration.
2. ☒ Claims 1-6, 18-42 have been cancelled.
3. ☐ Claims ok are allowed.
4. ☒ Claims 46 and 48-79 are rejected.
5. ☒ Claims 47 and 80-82 are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

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Claims 7-17 and 34-45 stand withdrawn from further consideration by the Examiner, 37 C.F.R. 1.142(b), as being for a nonelected invention. It is noted that applicants intended to cancel claims 7-17 in the amendment filed July 26, 1991.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification as originally filed, does not provide support for the inventions as is now claimed and the specification fails to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

The specification does not contain a written description of the term "amylin agonist" and therefore, the term is new matter.

The specification is not enabling as to the preparation and use of all possible compounds, peptides, proteins, etc. which are included in the term "Amylin agonist". It would require undue experimentation of one skilled in the art to prepare the indefinite number of compounds, peptides and proteins included by the term "Amylin Agonist" and then test each one to determine effectiveness in treating diabetes mellitus or hypoglycemia.

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Claims 46, 48, and 49-79 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 55-65 and 78-79 are rejected under 35 U.S.C. § 103 as being unpatentable over pages 10-11 of Applicants' specification.

The claims continue to be rejected for the reasons set forth on page 5 of the office action mailed December 10, 1990.

Claims 55=65 and 78-79 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are functional as to the point of novelty since the process is defined as bringing an effective amount of the

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amylin agonist into the form of a composition. The claims do not set forth the method steps of how the agonist are prepared in the desired form.

Applicants' declarations have been considered and are persuasive as to the effective use of amylin or amylin mixed with insulin in the claimed method of treatment. However, the declaration is not commensurate in scope with the claimed method of treatment using "amylin agonist" broadly.

Claims 47 and 80-82 are objected to as being dependent upon rejected claims. If applicants limited the pharmaceutical compositions and method of treatment claims to the use of amylin or a mixture of amylin and insulin, these claims would be allowable.

Any inquiry concerning this communication should be directed to Lester. L. Lee at telephone number (703) 308-3997.

Lee/vb
September 9, 1991

Lester L. Lee
LESTER L. LEE
PRIMARY PATENT EXAMINER
ART UNIT 189-B
189B